

REMARKS

Reconsideration of the present application is respectfully requested in view of the above Amendments and the following remarks. Claims 1-27 were pending. The Examiner has withdrawn claims 1, 2, 4-7, 10, 11, and 15-17. Applicants hereby cancel claims 1, 2, 5, and 6 without acquiescence to any rejection and without prejudice to prosecution of the cancelled subject matter in a related continuation, continuation-in-part, or divisional application. Applicants have amended claims 3, 8, 9, 12-14, 18, 19, 22, 23, and 25-27 and added new claims 28 and 29 to point out with particularity and clearly define certain embodiments of Applicant's invention. Applicant respectfully requests that new claim 28 be entered and considered because it is related to subject matter of elected Group D as set forth in the Office Action dated October 3, 2006 containing a Species Election Requirement. Withdrawn claims 7, 10, 11, and 15-17 have also been amended. Applicant respectfully requests that in view of the amendments submitted herewith that claims 15-17 be rejoined with claims 3, 8, 9, 12-14, and 18-27 currently under examination. No new matter has been added to the application. Support for the amended and new claims can be found throughout the specification, for example, at page 2, line 13 through page 3, line 15; page 4, lines 13-20; page 5, lines 9-20; page 8, lines 13-24; page 12, line 28 through page 13, line 4; and in the originally filed claims.

The specification has been amended to update the Cross-References to Related Applications section, to insert designations for trademarks, to correct typographical errors, and to amend the application consistent with amendments made in the parent application (see, for example, the amendment to the paragraph beginning at page 9, line 3 regarding the pQE30 vector). No new matter has been added to the application by these amendments.

Applicant thanks Examiner Devi for her time and query during an informal teleconference on August 17, 2007 regarding the relationship between the present application and U.S. Patent Application No. 09/151,409 (filed September 10, 1998), which issued as U.S. Patent No. 6,716,433 on April 6, 2004 ("parent application") and to which the present application claims priority. Applicant respectfully submits that the present application is a continuation application and not a continuation-in-part application of the parent application. No new matter was added to the specification at the time of filing the continuation application.

Furthermore, the amended claims and new claims submitted herewith do not go beyond the parent application as filed and the recitation of certain features is consistent with recitations in the issued claims in the parent and in the recently issued related divisional application (see U.S. Application No. 10/759,600, filed January 16, 2004, now issued as U.S. Patent No. 7,255,863 on August 14, 2007).

Applicant notes that the Office Action Summary does not indicate whether the drawings filed on February 17, 2004 were accepted or objected to by the Examiner. Applicant respectfully requests that the Examiner confirm that the drawings are accepted.

#### **OBJECTIONS TO THE SPECIFICATION**

The Examiner objected to the specification, stating that the first paragraph of the application does not recite the issued status of the parent application. The Examiner requires that the cross-reference section be updated accordingly.

Applicant submits that this objection to the specification has been obviated by the amendments submitted herewith. As indicated in the above Amendments to the Specification, the section, Cross-References to Related Applications, has been amended to recite the patent number and issue date of the parent application, U.S. Patent Application No. 09/151,409. Accordingly, Applicant respectfully requests that this objection be withdrawn.

The Examiner objected to the specification, asserting that the specification includes terms (such as the term, Gelvetol) that should be properly indicated as trademarks.

Applicant submits that the term, gelvatol, which is the more common spelling, is a name used in trade. The specification has been amended to indicate that the term gelvatol refers to polyvinyl alcohol. Applicant has used best efforts to identify trademarks and has amended the specification in accordance with M.P.E.P. § 608.01(v)(I) to indicate by trademark symbols (® or ™) which names, goods, and services may be proprietary marks. Applicant therefore submits that the specification meets the formality requirements and respectfully requests that this objection be withdrawn.

## **DOUBLE PATENTING**

The Examiner rejected claims 3, 9, 12-14, and 18 under the judicially created doctrine of obviousness-type double patenting, asserting that the claims are unpatentable over claims 3, 7, 9, 10, and 15, of U.S. Patent No. 6,716,433. The Examiner states that the conflicting claims are not identical; however, the Examiner asserts that the conflicting claims are not patentably distinct from each other because the “method claimed in the co-pending application” is encompassed within the scope of the pending claims in the present application.

As an initial matter, Applicant notes that the recitation in the Action regarding the “method claimed in the co-pending application” is likely a typographical error because the claims pending in the present application and the claims issued in the cited patent are directed to fusion polypeptides and compositions comprising the fusion polypeptides, not methods.

Applicant respectfully traverses this ground for rejection and submits that the present claims satisfy all requirements for patentability. Nevertheless, without acquiescing to the double patenting rejection, Applicant has enclosed a terminal disclaimer in compliance with 37 C.F.R. § 1.321(c), thereby obviating the double patenting rejection.

The Examiner provisionally rejected claims 22 and 23 under the judicially created doctrine of obviousness-type double patenting, asserting that the claims are unpatentable over claim 48 and claim 76 of co-pending U.S. Application No. 10/284,400. The Examiner states that the conflicting claims are not identical; however, the Examiner asserts that the claims are not patentably distinct from each other because the “method claimed in the co-pending application” is within the scope of claims 22 and 23.

As an initial matter, Applicant notes that the recitation in the Action regarding the “method claimed in the co-pending application” is likely a typographical error because claims 22 and 23 pending in the present application and claims 48 and 76 in the cited application relate to compositions comprising fusion polypeptides, not methods.

Applicant respectfully traverses this rejection and submits that the provisional rejection of claims 22 and 23 under the judicially created doctrine of obviousness-type double

patenting is moot in view of cancellation of claims 48 and 76 in U.S. Application No. 10/284,400.

Applicants note that U.S. Application No. 10/284,400 has now issued as U.S. Patent No. 7,270,827 on September 18, 2007.

**REJECTIONS UNDER 35 U.S.C. § 112, FIRST PARAGRAPH (WRITTEN DESCRIPTION, NEW MATTER)**

The Examiner rejected claims 3 and 25 under 35 U.S.C. § 112, first paragraph, asserting that the claimed subject matter is not described in the specification in a manner that reasonably conveys to a person skilled in the art that Applicant possessed the claimed embodiment at the time of filing the application.

With respect to claim 3, the Examiner asserts that the phrase “immunogenic polypeptide which is carboxy-terminal to the multivalent portion” is new matter. The Examiner also asserts that the phrase, “a carboxy-terminal reiterated immunogenic polypeptide, which is carboxy-terminal to the multivalent portion and is a reiteration of a polypeptide from the amino-terminal region of the multivalent portion” is not supported by the application as filed.

Applicant respectfully traverses this rejection and submits that the features of amended claim 3 are described in the application as filed and do not constitute new matter. Claim 3 is directed, in pertinent part, to a hybrid fusion polypeptide comprising a multivalent immunogenic portion fused to an immunogenic polypeptide carboxy-terminal to the multivalent immunogenic portion, which protects the immunogenicity of the multivalent immunogenic portion, wherein the multivalent immunogenic portion comprises six immunogenic amino-terminal polypeptides of Group A streptococcal M protein from six different Group A streptococcal serotypes, wherein the immunogenic polypeptide carboxy-terminal to the multivalent immunogenic portion is a reiteration of the immunogenic amino-terminal polypeptide from the amino terminus of the multivalent immunogenic portion, and wherein each of the six immunogenic amino-terminal polypeptides is at least 10 amino acids in length. Support for amended claim 3 may be found throughout the application, for example, at page 2, lines 13-24 and page 4, lines 13-20. No new matter has been added to the specification by this

amendment. Furthermore, claim 3 as submitted herewith does not go beyond the parent application as filed and is consistent with issued claims in the parent (U.S. Patent No. 6,716,433) and in the recently issued divisional application (see U.S. Application No. 10/759,600, filed January 16, 2004, now issued as U.S. Patent No. 7,255,863 on August 14, 2007).

The Examiner rejected claim 25 under 35 U.S.C. § 112, first paragraph, asserting that a “pharmaceutically acceptable excipient, carrier, stabilizer, or diluent” that “comprises at least one of a buffer, antioxidant, carbohydrate, and chelating agent” is not supported in the application as filed.

Applicant respectfully traverses this rejection and submits that claim 25 is sufficiently described in the specification. Nevertheless, without acquiescence to the rejection and to expedite prosecution of the present application, Applicant has amended claim 25. The amended claim relates to a composition comprising the fusion polypeptide, as recited, and at least one of a buffer, antioxidant, carbohydrate, and chelating agent (*see, e.g.*, page 12, line 28 through page 13, line 4). No new matter has been added to the specification by this amendment. Furthermore, amended claim 25 as submitted herewith does not go beyond the parent application as filed and is consistent with issued claims in the parent (U.S. Patent No. 6,716,433) and in the recently issued divisional application (see U.S. Application No. 10/759,600, filed January 16, 2004, now issued as U.S. Patent No. 7,255,863 on August 14, 2007).

Applicant therefore submits that the present continuation application meets the requirements for written description under 35 U.S.C. § 112, first paragraph, and respectfully requests that this rejection be withdrawn.

#### **REJECTIONS UNDER 35 U.S.C. § 112, SECOND PARAGRAPH**

The Examiner rejected claims 3, 8, 9, 12-14, and 18-27 under 35 U.S.C. § 112, second paragraph, asserting that the claims are indefinite.

**(a), (b), and (c):** The Examiner rejected claim 3, asserting that certain term and features are unclear. The Examiner asserts that the term “amino terminal region” is unclear. The Examiner also asserts that the limitation, “reiterated...polypeptide...is a reiteration of

polypeptide,” is redundant and confusing. The Examiner further asserts that the feature “a polypeptide from the amino-terminal region of the multivalent portion,” lacks clarity.

Applicant submits that in view of the amendments to claim 3 submitted herewith, this rejection is moot. Without acquiescence to the rejection, the term, “amino terminal region,” has been deleted from the claim and the redundancy has been removed. Amended claim 3 clearly and definitely sets forth, in pertinent part, that the claimed fusion polypeptide comprises a multivalent immunogenic portion fused to an immunogenic polypeptide carboxy-terminal to the multivalent immunogenic portion, which protects the immunogenicity of the multivalent immunogenic portion. The multivalent immunogenic portion comprises six immunogenic amino-terminal polypeptides of Group A streptococcal M protein from six different Group A streptococcal serotypes, wherein each of the six immunogenic amino-terminal polypeptides is at least 10 amino acids in length. Claim 3 further recites that the immunogenic polypeptide carboxy-terminal to the multivalent immunogenic portion is a reiteration of the immunogenic amino-terminal polypeptide from the amino terminus of the multivalent immunogenic portion.

**(d):** The Examiner rejected claim 22, asserting that the claim lacks proper antecedent basis for the limitation “a hybrid fusion polypeptide according to any one of claims....”

Applicant submits that in view of the amendments submitted herewith, this rejection is moot. Claim 22 has been amended to recite “*the* hybrid fusion polypeptide according to claim 3.”

**(e):** The Examiner rejected claim 23, asserting that the recitation of the word “with” in the phrase, “further comprising with an adjuvant,” is indefinite.

Applicant submits that this rejection has been overcome in view of the amendments to claim 23 submitted herewith. The word “with” has been deleted and the amended phrase recites, “further comprising an adjuvant.”

**(f) and (g):** The Examiner rejected claims 26 and 27, for lack of proper antecedent basis with respect to terms in the preamble.

Applicant has amended claim 26 to relate to and depend from the composition of claim 22. Claim 27, which depends from claim 26, has also been amended and is directed to the composition as recited.

**(h):** The Examiner rejected claims 8, 9, 12-14, and 18-27, asserting that because these claims depend from claim 3, which the Examiner asserts is indefinite, claims 8, 9, 12-14, and 18-27 are also indefinite.

Applicant submits that, as discussed above, amended claim 3 meets the requirements for definiteness; therefore all claims that depend from claim 3 are also clear and definite.

Applicant submits that in view of the amendments to the claims and the above remarks, the pending claims particularly point out and distinctly claim certain embodiments of Applicant's invention as required under 35 U.S.C. § 112, second paragraph. Applicant therefore respectfully requests that these rejections be withdrawn.

Applicant submits that all claims in the application are allowable. Favorable consideration and a Notice of Allowance are earnestly solicited.

The Director is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

Respectfully submitted,  
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